

Health and Human Services

370.401

of assurance for protection of human subjects.

370.302 Types of assurances.

Assurances may be one of two types:

(a) *Multiple Project Assurance (MPA)*. An MPA describes the oversight procedures applicable to all DHHS-supported human subjects activities within an institution having a significant number of concurrent projects. An MPA listed in OPRR's current "List of Institutions Which Have an Approved MPA" will be considered acceptable for purposes of this policy.

(b) *Single Project Assurance (SPA)*. An SPA describes the oversight procedures applicable to a single DHHS-supported human subjects activity. SPAs may be approved in modified form to meet unusual requirements. SPAs are not solicited from institutions with OPRR approved MPAs. Copies of proposals selected for negotiation and requiring one or more SPAs shall be forwarded to the Human Subjects Assurance Branch, OPRR, NIH MSC 7507, 6100 Executive Blvd., Room 3B01, Rockville, Maryland 20892, as early as possible so that timely action may be taken to secure the SPA(s).

370.303 Notice to offerors.

(a) Solicitations shall contain the notice to offerors in 352.270-8(a) whenever contract performance is expected to involve human subjects.

(b) IRB approval of proposals submitted by institutions having an OPRR-approved MPA should be certified in the manner required by instructions for completion of the contract proposal; or by completion of a DHHS Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration; or by letter indicating the institution's OPRR-assigned MPA number, the date of IRB review and approval, and the type of review (convened or expedited). The date of IRB approval must not be more than 12 months prior to the deadline for proposal submission.

(c) SPAs for contractors, subcontractors, or cooperating institutions generally will not be requested prior to determination that a contract proposal has been selected for negotiation. When an SPA is submitted, it provides cer-

tification for the initial contract period. No additional documentation is required. If the contract provides for additional years to complete the project, the noncompetitive renewal proposal shall be certified in the manner described in the preceding paragraph.

370.304 Contract clause.

The clause set forth in 352.270-8(b) shall be inserted in all solicitations and resultant contracts involving human subjects.

Subpart 370.4—Acquisitions Involving the Use of Laboratory Animals

370.400 Scope of subpart.

This subpart applies to all research, research training and biological testing activities involving live vertebrate animals conducted under contract (see Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), Rev. 1986, Repr. 1996).

370.401 Policy.

(a) It is the policy of the Department of Health and Human Services (DHHS) and the Public Health Service agencies that no contract involving live vertebrate animals shall be awarded until acceptable assurance has been given that the activity will be subject to initial and continuing review by an appropriate Institutional Animal Care and Use Committee (IACUC) as described in the PHS Policy at IV. B. 6. and 7. An applicable Full Animal Welfare Assurance or Interinstitutional Agreement/Assurance, approved by the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), shall be required of each contractor, subcontractor, or cooperating institution having responsibility for animal care and use involved in performance of the contract (see PHS Policy II., IV. A., and V. B.).

(b) The OPRR, NIH, is responsible for negotiating assurances covering all DHHS/PHS-supported or DHHS/PHS-conducted activities involving the care and use of live vertebrate animals. Contracting officers shall be guided by